

**DEPARTMENT OF HEALTH AND HUMAN SERVICES**

**Food and Drug Administration**

[Docket No. 2001D-0489] (formerly Docket No. 01D-0489)

*SPM*  
JUL 28 2005  
Display Date \_\_\_\_\_  
Publication Date \_\_\_\_\_  
Comments *Spence*

**Agency Information Collection Activities; Announcement of Office of Management and Budget Approval; Guidance for Clinical Trial Sponsors: Establishment and Operation of Clinical Trial Data Monitoring Committees**

**AGENCY:** Food and Drug Administration, HHS.

**ACTION:** Notice.

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**SUMMARY:** The Food and Drug Administration (FDA) is announcing that a collection of information entitled "Guidance for Clinical Trial Sponsors: Establishment and Operation of Clinical Trial Data Monitoring Committees" has been approved by the Office of Management and Budget (OMB) under the Paperwork Reduction Act of 1995.

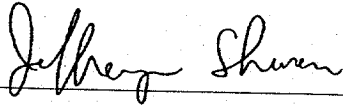
**FOR FURTHER INFORMATION CONTACT:** Jonna Capezzuto, Office of Management Programs (HFA-250), Food and Drug Administration, 5600 Fishers Lane, Rockville, MD 20857, 301-827-4659.

**SUPPLEMENTARY INFORMATION:** In the **Federal Register** of December 30, 2005 (70 FR 77403), the agency announced that the proposed information collection had been submitted to OMB for review and clearance under 44 U.S.C. 3507. An agency may not conduct or sponsor, and a person is not required to respond to, a collection of information unless it displays a currently valid OMB control number. OMB has now approved the information collection and has assigned OMB control number 0910-0581. The approval expires on March 31, 2009.

A copy of the supporting statement for this information collection is available on the Internet at <http://www.fda.gov/ohrms/dockets>.

Dated: JUL 21 2006

July 21, 2006.



Jeffrey Shuren,  
Assistant Commissioner for Policy.

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